EXHIBIT VIII

FDA APPROVAL LETTER

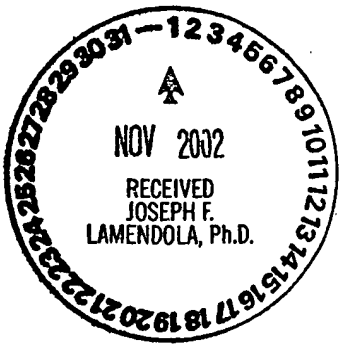
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-445

Schering Corporation, Agent for
MSP Singapore Company, LLC
Attention: Joseph F. Lamendola, Ph.D.
Vice President, US Regulatory Affairs
2000 Galloping Hill Road
Kenilworth, NJ 07033



Dear Dr. Lamendola:

Please refer to your new drug application (NDA) dated December 27, 2001, received December 27, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zetia (ezetimibe) Tablets, 10 mg.

We acknowledge receipt of your submissions dated January 9 and 30, February 11, March 4, April 2, 5, 19 (2), 24, and 26, May 8, 9, and 16, June 14 (2) and 28, July 2, 3, 9, 15, 19, 22, 24, and 26, August 2, 5, 6, 21, 23 (2), and 27, September 9, 12, 13, 24, 25, 26, and 30, and October 1, 2, 3 (2), 10, 14, 15, 21, 22, 23, and 24, 2002.

This new drug application provides for the use of Zetia (ezetimibe) Tablets, 10 mg, for the following indications:

> Primary hypercholesterolemia – as adjunctive therapy to diet for reduction of elevated total-C, LDL-C and Apo B in patients with primary (heterozygous familial and non-familial) hypercholesterolemia either alone or with an HMG-Co A reductase inhibitor.
>
> Homozygous familial hypercholesterolemia – in combination with either atorvastatin or simvastatin, as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or, if such treatments are unavailable, in combination with either atorvastatin or simvastatin alone.
>
> Homozygous familial sitosterolemia – as adjunctive therapy to diet for the reduction of elevated sitosterol and campesterol levels.

We completed our review of this application, as amended, and it is approved, effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted October 24, 2002, patient package insert submitted October 22, 2002, immediate container and carton labels submitted October 14, 2002). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-445.**" Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitment in your submission dated October 21, 2002.

Description of Commitment

An efficacy and safety study of no longer than 12 weeks in non-Caucasian patients treated with Zetia.

Draft Protocol Submission:	Within 3 months of the date of this letter
Study Start:	Within 12 months of the date of this letter
Final Report Submission:	Within 26 months of the date of this letter

Submit the clinical protocol to your IND for this product. Submit the study final report to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of the commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into the study. All submissions, including supplements, relating to this postmarketing study commitment must be prominently labeled **"Postmarketing Study Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."**

The text in italics below addresses the application of FDA's Pediatric Rule at 21 CFR 314.55 to this NDA. The Pediatric Rule has been challenged in court. On October 17, 2002, the court ruled that FDA did not have the authority to issue the Pediatric Rule and has barred FDA from enforcing it. The government has not yet decided whether to seek a stay of the court's order. In addition, the government has not yet decided whether to appeal the decision; an appeal must be filed within 60 days. **Therefore, this letter contains a description of the pediatric studies that would be required under the Pediatric Rule, if the Pediatric Rule remained in effect and/or was upheld on appeal.** Please be aware that whether or not these pediatric studies will be required will depend upon the resolution of the litigation. FDA will notify you as soon as possible as to whether this application will be subject to the requirements of the Pediatric Rule as described below. In any event, we hope you will decide to conduct these pediatric studies to provide important information on the safe and effective use of this drug in the relevant pediatric populations.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens must contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (21 CFR 314.55).

Based on information submitted, we conclude the following:

For:

Primary hypercholesterolemia – as adjunctive therapy to diet for reduction of elevated total-C, LDL-C and Apo B in patients with primary (heterozygous familial and non-familial) hypercholesterolemia either alone or with an HMG-Co A reductase inhibitor.

Homozygous familial hypercholesterolemia – in combination with atorvastatin or simvastatin, as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or, if such treatments are unavailable, in combination with atorvastatin or simvastatin alone.

Homozygous familial sitosterolemia – as adjunctive therapy to diet for the reduction of elevated sitosterol and campesterol levels.

- *We are waiving the pediatric study requirement for this application for patients younger than 10 years of age.*
- *We are deferring submission of pediatric studies for patients 10 to 16 years of age until December 2, 2004.*

The pediatric exclusivity provisions of FDAMA as reauthorized by the Best Pharmaceuticals for Children Act are not affected by the court's ruling. Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products (pediatric exclusivity). You should refer to the Guidance for Industry on Qualifying for Pediatric Exclusivity (available on our web site at www.fda.gov/cder/pediatric) for details. If you wish to qualify for pediatric exclusivity, you should submit a "Proposed Pediatric Study Request". FDA generally does not consider studies submitted to an NDA before issuance of a Written Request as responsive to the Written Request. Applicants should obtain a Written Request before submitting pediatric studies to an NDA.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Metabolic and Endocrine Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

We also remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call William C. Koch, R.Ph., Regulatory Project Manager, at (301) 827-6412.

Sincerely, /s/

{See appended Robert Meyer
10/25/02 05:11:58 PM

Robert J. Meyer, M.D.
Director
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert Meyer
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